

PSJ1 Exh 16

Chunderlik Exhibit

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3/8/21 Carrie Campbell, RDR

exhibitsticker.com



Pharmacy Compliance

By George Chunderlik

Pharmacy Board Review 2013

Required Legal Education

- HIPAA Privacy
- HIPAA Security
- HiTech Act
- MethGuard
- Fraud, Waste & Abuse (annual)
- OSHA (annual)



Additional Required Education

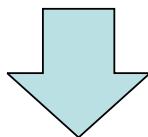
- TIRF REMS Education
- Isotretinoin Risk Mgt. (*iPLEDGE*)
- DEA Audit – What the Pharmacist Needs to Know
- Point of Sale Policy Review
- Giant Eagle Specialty Pharmacy



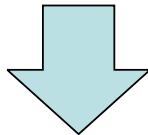
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Learning Resource Center

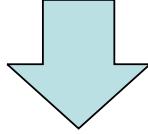
GE Central



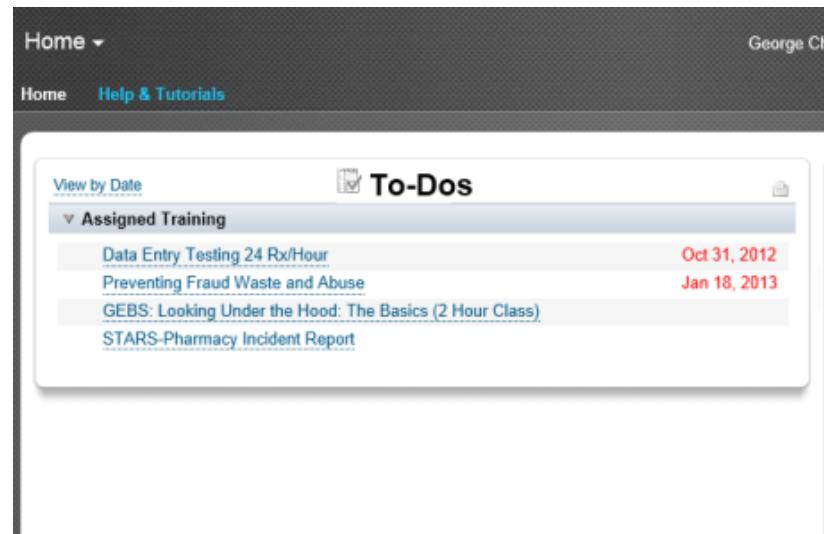
MyHRConnection



My Resources



“Enter Here” on Talent Development Logo



First Assignment

- Access the Learning Resource Center to check e-learing profile
- Send an email to George Chunderlik
 - Verify completion of all legally required legal education
 - Add additional CBTs to e-learing profile

George.Chunderlik@gainteagle.com



Return to Stock

- Purpose
 - Establish procedures to return medications to stock from Will Call
- Procedure
 - A report will be generated daily listing medications to be removed from the will call and returned to stock
 - Will call bin is reviewed manually weekly
 - Prescriptions are credit returned
 - The bottle is labeled with the NDC of the contents and HIPAA information is blacked out then placed on the shelf to be re-dispensed within the legal time limitation
 - PA – 6 months
 - OH – 90 days
 - MD – 1 year
 - WV – 30 days



Outdate, Damage and Recall Return Policy

- Purpose
 - To ensure that outdated and/or damaged product is pulled from active inventory
- Procedure
 - Each Team Member is assigned a section of the inventory to check for expiring product and clean the shelves
 - All product expiring the current month or following two months (expiring within 90 days) is removed from active inventory
 - Damaged or recalled products are removed from active inventory as discovered/notified
 - Removed products are counted and the on-hand qtys. are updated in the computer
 - Amber bottles must have the patient information blackened out
 - Removed products are returned once per quarter via our return service provider



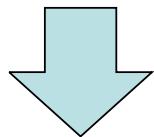
State Laws, Rules & Regulations

- Each pharmacist is responsible for knowing and abiding by all federal and state rules and regulations.
- Available resources are found on GE Central which include:
 - State Board Websites
 - Links to additional information governing specific areas of practice
 - Federal Websites
 - Drug Enforcement Agency (DEA)
 - FDA

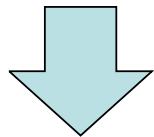


State Laws, Rules & Regulations

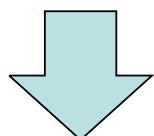
GE Central



**View Pharmacy
Library**



**Product & Merchandising
Info**



Websites

The screenshot shows the GIANT EAGLE GE Library interface. At the top, there's a navigation bar with links for Home, Applications, Navigate To, Reports, Tools and Resources, Learning Center, Favorites, and Help. A search bar is also present. The main content area has a heading 'Websites Features:' followed by the message 'No Features at this time.' Below this, there's a section titled 'Websites' with a sub-section for 'Product websites and related information available on the Internet.' A table lists various documents with their names, types, and modification dates:

Type	Name	Modified
link	Ohio Administrative Code - Pharmacy Specific	8/16/2012 8:01 PM
link	Ohio Bureau of Workers Compensation	8/16/2012 8:00 PM
link	Ohio Department of Job and Family Services	5/30/2013 12:55 PM
link	Ohio Laws and Rules	8/16/2012 7:59 PM
link	Ohio Medicaid Program	8/16/2012 3:32 PM
link	Ohio State Board of Pharmacy	11/28/2012 1:30 PM
link	PACE - Pennsylvania Department of Aging	7/28/2011 8:47 PM
link	Pennsylvania Bulletin	11/8/2012 3:48 PM
link	Pennsylvania Code - Chapter 25	5/30/2013 12:55 PM
link	Pennsylvania Code - Chapter 27	6/15/2011 3:38 PM
link	Pennsylvania Department of State Professional Licensure	7/28/2011 2:09 PM
link	Pennsylvania State Board of Pharmacy	5/30/2013 12:55 PM
link	Pharmacists Letter	5/30/2013 12:55 PM

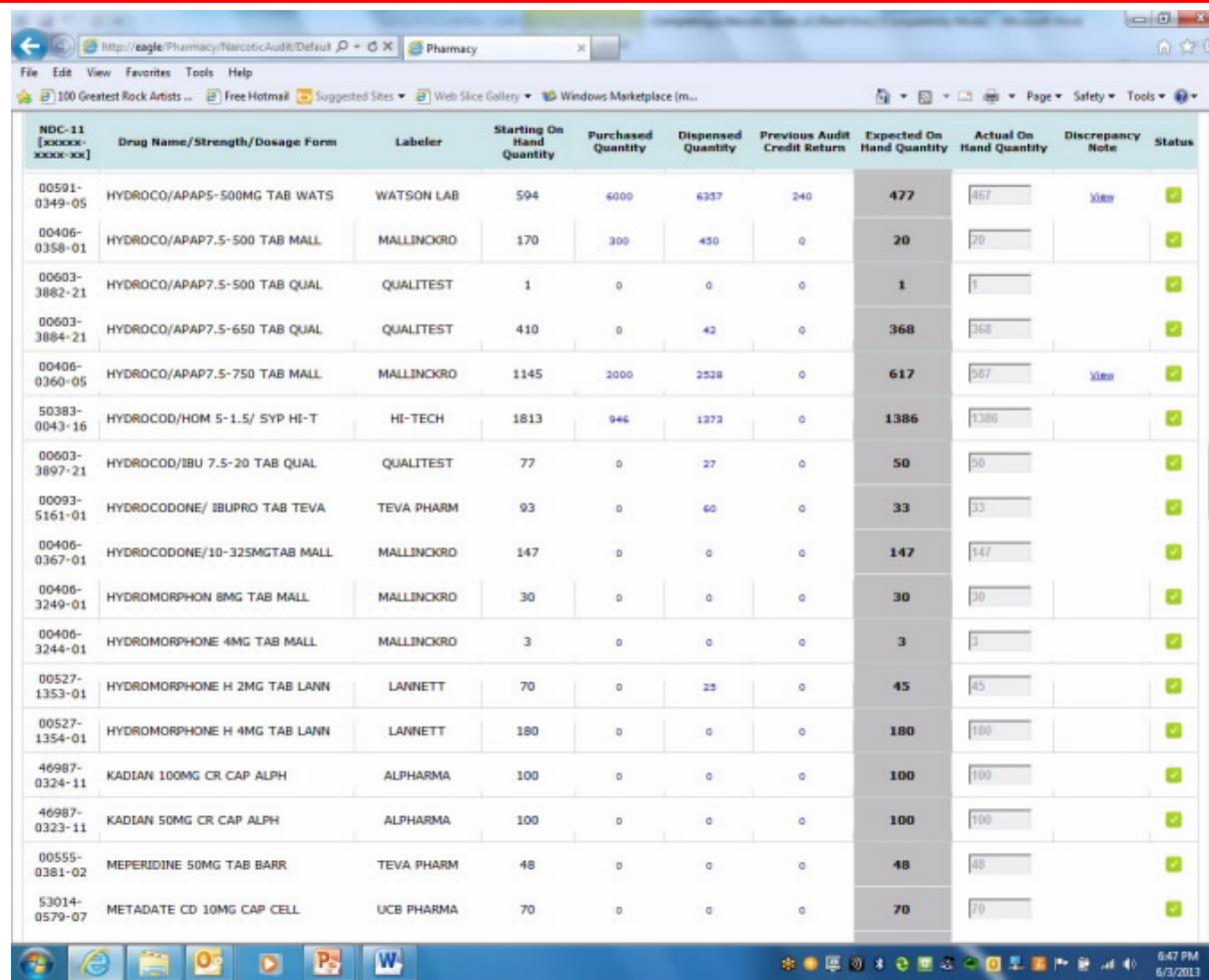


Controlled Drug Audits

- Required to be completed every month
 - Exact count of all schedule II narcotics
 - Hydrocodone containing products
 - Suboxone products
 - Inventory is tracked by NDC rather than medication name (GPI) making it easier to identify reasons for discrepancies.



Controlled Drug Audits



The screenshot shows a Microsoft Internet Explorer browser window with the address bar displaying "http://eagle/Pharmacy/NarcoticAudit/Default.aspx". The title bar says "Pharmacy". The main content area is a grid-based table for tracking controlled drug audits. The columns are labeled: NDC-11 [xxxxx-xxxx-xx], Drug Name/Strength/Dosage Form, Labeler, Starting On Hand Quantity, Purchased Quantity, Dispensed Quantity, Previous Audit Credit Return, Expected On Hand Quantity, Actual On Hand Quantity, Discrepancy Note, and Status. The table contains approximately 20 rows of data, each representing a different drug item with its details and audit status.

NDC-11 [xxxxx- xxxx-xx]	Drug Name/Strength/Dosage Form	Labeler	Starting On Hand Quantity	Purchased Quantity	Dispensed Quantity	Previous Audit Credit Return	Expected On Hand Quantity	Actual On Hand Quantity	Discrepancy Note	Status
00591-0349-05	HYDROCO/APAP5-500MG TAB WATS	WATSON LAB	594	6000	6357	240	477	467	View	✓
00406-0358-01	HYDROCO/APAP7.5-500 TAB MALL	MALLINCKROD	170	300	450	0	20	20		✓
00603-3882-21	HYDROCO/APAP7.5-500 TAB QUAL	QUALITEST	1	0	0	0	1	1		✓
00603-3884-21	HYDROCO/APAP7.5-650 TAB QUAL	QUALITEST	410	0	42	0	368	368		✓
00406-0360-05	HYDROCO/APAP7.5-750 TAB MALL	MALLINCKROD	1145	2000	2528	0	617	587	View	✓
50383-0043-16	HYDROCOD/HOM 5-1.5/ SYP HI-T	HI-TECH	1813	946	1373	0	1386	1386		✓
00603-3897-21	HYDROCOD/IBU 7.5-20 TAB QUAL	QUALITEST	77	0	27	0	50	50		✓
00093-5161-01	HYDROCODONE/ IBUPRO TAB TEVA	TEVA PHARM	93	0	60	0	33	33		✓
00406-0367-01	HYDROCODONE/10-325MGTAB MALL	MALLINCKROD	147	0	0	0	147	147		✓
00406-3249-01	HYDROMORPHON 8MG TAB MALL	MALLINCKROD	30	0	0	0	30	30		✓
00406-3244-01	HYDROMORPHONE 4MG TAB MALL	MALLINCKROD	3	0	0	0	3	3		✓
00527-1353-01	HYDROMORPHONE H 2MG TAB LANN	LANNETT	70	0	25	0	45	45		✓
00527-1354-01	HYDROMORPHONE H 4MG TAB LANN	LANNETT	180	0	0	0	180	180		✓
46987-0324-11	KADIAN 100MG CR CAP ALPH	ALPHARMA	100	0	0	0	100	100		✓
46987-0323-11	KADIAN 50MG CR CAP ALPH	ALPHARMA	100	0	0	0	100	100		✓
00555-0381-02	MEPERIDINE 50MG TAB BARR	TEVA PHARM	48	0	0	0	48	48		✓
53014-0579-07	METADATE CD 10MG CAP CELL	UCB PHARMA	70	0	0	0	70	70		✓



Pseudoephedrine (PSE) Monitoring

Pseudoephedrine Limits (in GRAMS)

Pharmacy Selling Limits				Customer Purchase Limits		
State	Daily	Rolling 30 days	Rolling Year	Daily	Rolling 30 days	Rolling Year
WV	3.6	7.2	48	3.6	7.2	48
OH	3.6	9		3.6	9	
PA	3.6				9	
MD	3.6				9	



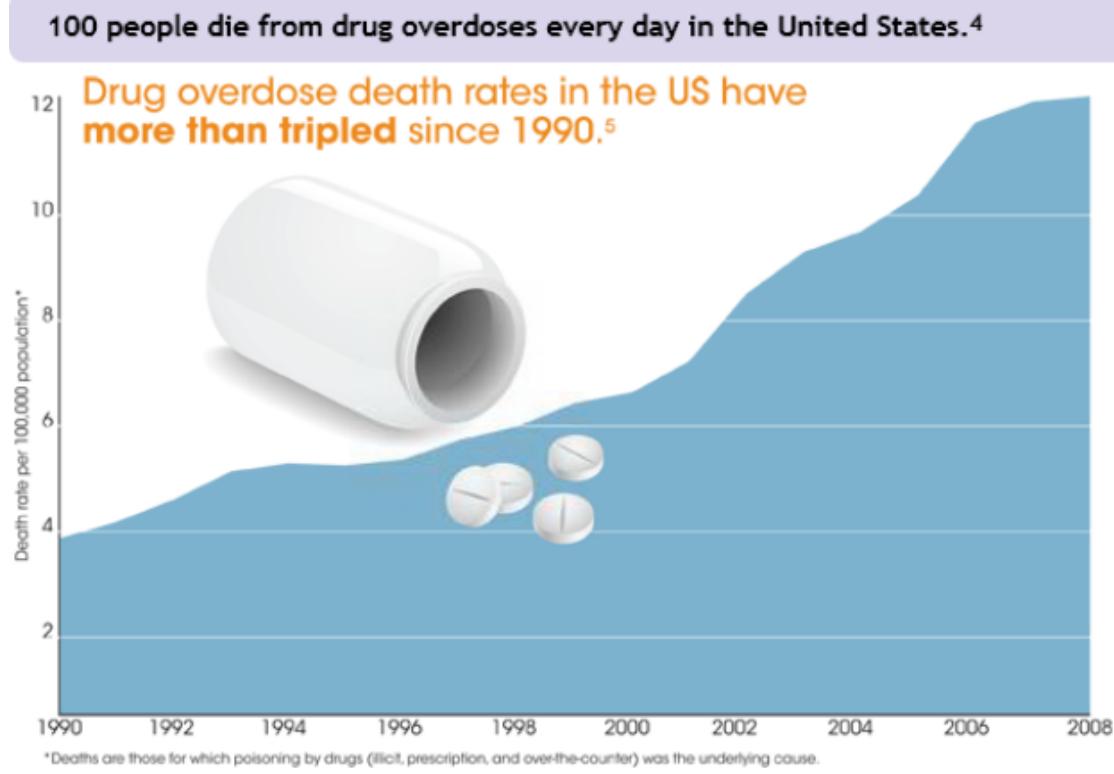
Pseudoephedrine (PSE) Monitoring

- Pennsylvania and Maryland currently use manual log book to monitor and record sales
- WV and Ohio electronically track sales of PSE products via the National Precursor Log Exchange (NPLEX)
 - WV accesses Appriss web portal directly
 - OH stores utilize POS system
 - All stores anticipated to be utilizing POS to electronically track PSE sales by the end of the calendar year.



Prescription Drug Abuse Epidemic

- According to the Centers for Disease Control (CDC)



Prescription Drug Abuse Epidemic

- In 2009 deaths from prescription drug overdoses exceed deaths from auto accidents for the first time ever
- Over 20% of Americans admit to abusing prescription drugs
- Prescription drugs are now the recognized gateway drugs to “heroin” and other illegal drugs



Controlled Substance Dispensing

Statement of Purpose

- It is our responsibility both as healthcare professionals and as a company to do all we can to curb the misuse of prescriptions drugs
- The DEA in its efforts to control the illegal use of prescription drugs is holding pharmacists *personally* accountable for their decisions and actions when dispensing controlled substances.



Corresponding Responsibility

- Prescribers have a duty to write prescriptions both legally and responsibly
- Pharmacists have an acknowledged **corresponding responsibility** to “exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription”



Due Diligence

- Verify the prescription is valid and written in the usual course of professional treatment
 - Phone book, internet site, operator assistance
- The prescription is appropriate (dosage and quantity are reasonable for the patient's diagnosis)
 - Large dosages and/or quantities are indicators for misuse
 - If applicable record the reason for the high dose on the rx
- The prescription is timely (on schedule to be filled based on previous prescription history)
 - Early refills and multiple doctors are signs for misuse



Due Diligence con't

- Verify the prescribers DEA registration
 - Use the formula to validate DEA number
- Access the information within the state's Prescription Drug Monitoring Program (PDMP) if available
 - OARRs in Ohio
- Review prescription for alterations/changes
- Request diagnosis, treatment plans, patient contract

DOCUMENT! DOCUMENT! DOCUMENT!!!!

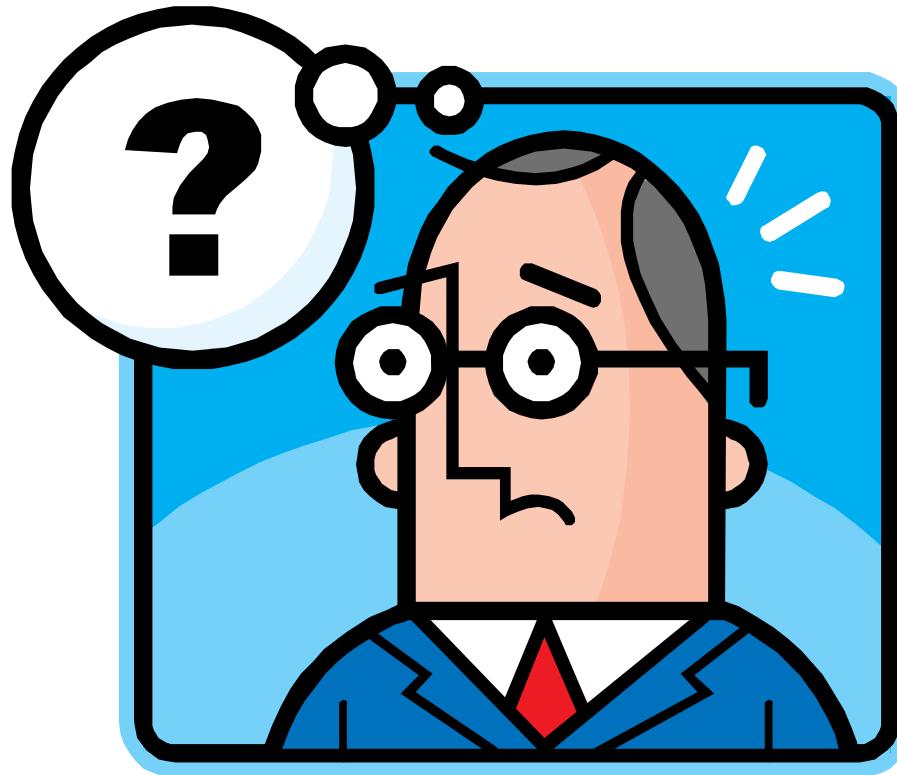


Promise of Support

- Giant Eagle supports the professional judgment of each Pharmacist Team Member
- If after performing required due diligence, any pharmacist refuses to fill a prescription for a medication due to concerns of validity and/or misuse, Giant Eagle will support the decision



Questions



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Congratulations & Good Luck



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